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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,045	06/30/2006	Alessandro Moretta	INN-133	6062

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
02/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,045	MORETTA ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *56-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

1. Applicant's amendment filed 12/30/05 is acknowledged and has been entered.

2. Restriction is required under 35 U.S.C. 121 and 372.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Warren *et al* (Tissue Antigens, 2000, 55 (Suppl 1) : 80-81, IDS reference) teach monoclonal antibodies that react with three different KIR receptor gene products, and wherein the antibodies are capable of blocking inhibitory KIR to permit enhanced cytotoxicity of an NK cell line on targets expressing the ligand HLA-Cw7.

I. Claims 56-59, drawn to a composition of matter comprising an isolated antibody that binds at least two different human inhibitory KIR receptor gene products and is capable of neutralizing KIR-mediated inhibition of NK cell cytotoxicity in NK cells expressing at least one of the said two different human inhibitory KIR receptors, and the hybridoma that produces said antibody.

II. Claims 60-65, drawn to a method of producing an antibody binds at least two different human inhibitory KIR receptor gene products and is capable of neutralizing KIR-mediated inhibition of NK cell cytotoxicity in NK cells expressing at least one of the said two different human inhibitory KIR receptors, wherein the method comprises selecting from a library an antibody or fragment thereof that cross-reacts with at least two different human inhibitory KIR2DL receptor gene products and selecting that antibody that is capable of neutralizing KIR-mediated inhibition of NK cell cytotoxicity on a population of NK cells expressing at said at least two different human inhibitory KIR receptors.

III. Claims 66 and 67, drawn to potentiating NK cell activity in a patient comprising administering a composition comprising an antibody that binds at least two different human inhibitory KIR receptor gene products and is capable of neutralizing KIR-mediated inhibition of NK cell cytotoxicity in NK cells expressing at least one of the said two different human inhibitory KIR receptors.

IV. Claim 68, drawn to a method of detecting the presence of NK cells bearing an inhibitory KIR on their cell surface in a biological sample or a living organism, comprising contacting the biological sample or living organism with an antibody that binds at least two different human inhibitory KIR receptor gene products, and wherein the antibody is capable of neutralizing KIR-mediated inhibition of NK cell cytotoxicity in NK cells expressing at least one of said two different human inhibitor KIR receptors, wherein the antibody is conjugated or covalently bound to a detectable moiety and detecting the presence of said antibody.

V. Claim 69, drawn to a method of purifying from a sample, NK cells bearing an inhibitory KIR their cell surface, comprising contacting a sample with an antibody bound to a solid support, said antibody binds at least two different human inhibitory KIR receptor gene products, and wherein the antibody is capable of neutralizing KIR-mediated inhibition of NK cell cytotoxicity in NK cells expressing at least one of said two different human inhibitor KIR receptors, and eluting the bound NK cells from the solid support.

3. The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

4. If Applicant elects Invention I: Applicant is required to (1) elect a single disclosed species (*i.e.*, an ultimate species of isolated antibody, for example, the monoclonal antibody produced by hybridoma DF200, AND the hybridoma that produces said antibody, AND any additional components, for example a therapeutic agent that is IL-2, and a pharmaceutically acceptable carrier, AND IF the antibody is conjugated or covalently bound to ONE of a toxin, detectable moiety or a solid support. In addition, Applicant is required to specificy which KIR receptors the antibody binds to and what inhibition the antibody is capable of performing , for example the KIR2DL1 and KIR2DL2/3 and inhibition of binding of an HLA-C allele molecule having a Lys residues at position 80 to a human KIR2DL1 receptor and the binding of an HLA-C allele molecule having an Asn residue at position 80 to human KIR2DL2/3 receptors) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

Applicant is requested to list which portions of base claim 56 (*i.e.*, (a)-(l)) read on the elected species.

These species are distinct because their structures are different.

5. If Applicant elects Invention II: Applicant is required to (1) elect a single disclosed species of at least two human inhibitory KIR receptor gene products to which the antibody to be made in the claimed method is directed (for example, the KIR2DL1 and KIR2DI2/3 receptor gene products) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

6. If Applicant elects Invention III: Applicant is required to (1) elect a single disclosed species of antibody to be used in the claimed method **AND** any further method steps that are not recited in base claim 60, such as one or more of the steps recited in claims 61 and 63-65 (*i.e.*, an ultimate species of isolated antibody, for example, the monoclonal antibody produced by hybridoma DF200, and for example, the method steps of claims 64 and 65) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Applicant elects Invention IV: Applicant is required to (1) elect a single disclosed species of antibody to be used in the claimed method of detection **AND** whether the detection is accomplished with a biological sample or with a living organism, AND a specific detectable moiety (*i.e.*, an ultimate species of isolated antibody, for example, the monoclonal antibody produced by hybridoma DF200, and for example detection is accomplished with a biological sample) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

8. If Applicant elects Invention V: Applicant is required to (1) elect a single disclosed species of antibody to be used in the claimed method of detection (*i.e.,* an ultimate species of isolated antibody, for example, the monoclonal antibody produced by hybridoma DF200) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

9. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. Each antibody has a different sequence and the method steps are different steps. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (*e.g.,* searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art,

the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Eileen B. O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Group 1640/Technology Center 1600
February 12, 2009

/G.R. Ewoldt/
Primary Examiner, Art Unit 1644